SEP 2 7 2002

K022115

SECTION II 510(k) SUMMARY OF SAFETY And EFFECTIVENESS

SEP 2 7 2002

CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir

Submitter Information:

This submission was prepared in June 2002 by:
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This submission was prepared for:
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Fujinomiya city, Shizuoka Pref.
Japan 418-0015

Device Name(s)/Classifications:

Proprietary Name	Classification Name	Common Name
CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Oxygenator
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
	Cardiopulmonary Bypass Defoamer (Code: DTP)	Defoamer
	Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter (Code: JOD)	Blood Filter
	Cardiopulmonary Bypass Stopcock, Manifold, Fitting (Code: DTL)	Sampling Manifold with Stopcocks

Predicate Device:
The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following devices:

Medtronic Minimax Plus Oxygenator w/wo Hardshell Reservoir – (K933586).
Cobe VPCML Plus Oxygenator with Hardshell Reservoir – (K842908).

Intended Use:
The CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integral heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The (detachable) hardshell reservoir is used to store blood during extracorporeal circulation from both venous line and the cardiotomy line (via gravity or vacuum assisted venous drainage procedures). The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal.

The CAPIOX® RX05 Oxygenator with/without Hardshell Reservoir can be used in procedures lasting up to 6 hours.

The CAPIOX® RX05 is for use with neonatal and infant patients when the required blood flow rate will not exceed 1.5 L/min.

Principles of Operation and Technology:
The design of the CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir is such that blood is collected into the reservoir via gravity or external vacuum. Blood may enter via the venous inlet port and/or the cardiotomy inlet port. The reservoir contains filtering devices to remove particulate matter and air. Blood is then pumped from the reservoir into the heat exchanger device whereby blood temperature is controlled. After the blood exits the heat exchanger, it enters the oxygenator device whereby gas transfer (introduction of oxygen and removal of carbon dioxide) occurs. After gas transfer has occurred, the blood exits the device and is pumped towards the patient.

Design and Materials:
The design of the CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir provides a semi-integral device whereby the oxygenator and heat exchanger are joined together, while the hardshell reservoir can be detached from the device assembly.

The materials that are used in the construction of the CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir include, but are not limited to, polycarbonate, stainless steel, polyvinylchloride, polyurethane, polyester, polypropylene, polyethylene and X-Coating.

Performance Evaluations:
Clinical studies are not necessary to demonstrate substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- Gas Transfer
- Effects on Blood Components (Hemolysis)
- Pressure Drop
- Mechanical Integrity
- Static Priming Volume
- Heat Exchanger Performance
- Defoaming
- Filtration Efficiency
- Flow Rate

Substantial Equivalence Comparison:
The CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir is substantially equivalent to the predicate devices as follows:

- Intended Use: The intended uses of the subject device and the predicate devices (Medtronic and Cobe) are essentially the same. The oxygenator devices are used to provide for gas exchange between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

  Each of the integral heat exchangers is used to warm or cool blood and/or perfusion fluid as it flows through the device.

  The respective hardshell reservoirs are each used to collect and store blood during the bypass procedure. Filters are present in each device to facilitate air and particulate removal.

  Each of the devices may be used with the neonatal patient population.

- Principles of Operation and Technology: The technology of the subject device and the predicate devices (Medtronic and Cobe) are essentially identical. The devices operate in a manner where blood is collected into the reservoir. The blood may enter the reservoir via the venous inlet or the cardiotomy inlet. The reservoirs each contain filtering/defoaming devices that facilitate the removal of particulate matter and air. Blood is then pumped from the reservoir into the heat exchanger device whereby

blood temperature is controlled with the use of an external water bath. After the blood exits the heat exchanger, it enters the oxygenator device whereby gas transfer occurs (i.e., introduction of oxygen; removal of carbon dioxide). The transfer process occurs via diffusion across the walls of the hollow fiber membranes contained within the oxygenator. After gas transfer has occurred, the blood exits the devices and is pumped towards the patient.

The CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir may be used in procedures that utilize Vacuum Assist procedures to facilitate blood flow into the hardshell reservoir. Use of the device with Vacuum Assisted procedures does not raise any new issues of safety and/or effectiveness. To our knowledge, the Cobe and Medtronic devices are not used with Vacuum Assist procedures.

- Design and Materials: The design and the materials of the CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir and the predicate device are essentially the same. The design of each device is similar in that they each contain a hardshell reservoir for collection of blood, a heat exchanger for temperature control, and an oxygenator for gas transfer. Such a design is common among oxygenating devices on the market.

  The devices are manufactured with variations of plastics, adhesives, urethanes, polypropylene, stainless steel, etc. The RX05 device contains X-Coating, which is a biocompatible surface coating that reduces platelet adhesion to the device. The use of X-Coating has been demonstrated as safe and raises no new issues of safety and/or effectiveness.

- Performance: Comparisons of the performance of the CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir and the predicate devices were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the devices.

Substantial Equivalence Summary:
In summary, the CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir and the predicate devices are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject device and the predicate devices (Medtronic Minimax, K933586 and Cobe VPCML, K842908) do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}. Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo conducted biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- Terumo conducted studies for materials characterization, including physico-chemical profiles of aged and nonaged devices.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

Conclusion:
In summary, the CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate devices, the Medtronic Minimax (K933586) and the Cobe VPCML Plus (K842908).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2002

Terumo Cardiovascular Systems Corporation
c/o Gary A. Courtney, MBA, RAC
Sr. Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, Maryland 21921

Re: K022115
Trade Name: CAPIOX® rx05 Hollow Fiber Oxygenator with/without Hardshell Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: June 28, 2002
Received: July 1, 2002

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **CAPIOX® RX05 Hollow Fiber Oxygenator with/without Hardshell Reservoir**

Indications For Use:

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Garry A. Courtney 6-28-02

Garry A. Courtney, MBA, RAC
Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022115

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)